Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Endoscopic mucosal tissue sampling.

Bibliographic Source(s)

ASGE Standards of Practice Committee, Sharaf RN, Shergill AK, Odze RD, Krinsky ML, Fukami N, Jain R, Appalaneni V, Anderson MA, Ben-Menachem T, Chandrasekhara V, Chathadi K, Decker GA, Early D, Evans JA, Fanelli RD, Fisher DA, Fisher LR, Foley KQ, Hwang JH, Jue TL, Ikenberry SO, Khan KM, Lightdale J, Malpas PM, Maple JT, Pasha S, Saltzman J, Dominitz JA, Cash BD. Endoscopic mucosal tissue sampling. Gastrointest Endosc. 2013 Aug;78(2):216-24. [73 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (++++, +++O, ++OO, and +OOO) and for the strength of the recommendations ("recommends" or "suggests") are provided at the end of the "Major Recommendations" field.

Tissue Sampling Recommendations and Suggestions

Disease	Tissue Sampling	Strength	Evidence
Esophagus			
GERD	Targeted biopsies of irregular mucosa, if clinically warranted	S	++OO
BE*	Surveillance of nondysplastic BE: 4-quadrant biopsies every 2 cm with large-capacity forceps for length of Barrett's mucosa	S	++OO
	Surveillance of BE with LGD: 4-quadrant biopsies every 1-2 cm with large-capacity forceps for length of Barrett's mucosa	R	+++O
	Surveillance of BE with HGD: 4-quadrant biopsies every 1 cm with large-capacity forceps for length of Barrett's mucosa	R	+++O
EoE*	2-4 biopsies from proximal esophagus	S	++OO

Disease	Tissue Sampling	Strength	Evidence
	2-4 biopsies from distal esophagus Biopsies of gastric antrum and duodenum when EG suspected Biopsies should not be placed in Bouin's preservative		
Infectious esophagitis	Viral esophagitis Multiple biopsies from margin and base of visualized ulcers Specimens should be sent for standard histology, IHC, and possibly viral culture and PCR	S	++OO
	Candidal esophagitis Multiple biopsies of affected area Cytologic brushing complementary to biopsy	S	++OO
Stomach			
Helicobacter pylori (*H pylori*) infection*	Urease test 1-2 biopsies: 5 cm proximal to the pylorus on the lesser curvature near the angularis or on the greater curve opposite the angularis	S	++OO
	A negative urease test result should be confirmed with further testing for *H pylori*	S	++OO
	Histologic diagnosis 2 approaches: 3 biopsies: 1 from the angulus corpus-antrum junction, 1 from the greater curvature of the corpus, 1 from the greater curvature of the antrum	S	++OO
	or		
	Updated Sydney Protocol 5 biopsies: 1 from the antrum 2-3 cm from the pylorus lesser curvature, 1 from the antrum 2-3 cm from the pylorus greater curvature, 1 from the corpus 8 cm from the cardia lesser curvature, 1 from the corpus 8 cm from the cardia greater curvature, 1 from the angularis	S	++OO
	If *H pylori* positive, perform biopsy protocol for EMAG (below)	S	++OO
EMAG*	Best data with 7-12 biopsies: 4-quadrant biopsies from antrum (2–3 cm proximal to pylorus), 2 from the angularis, 4 from the mid corpus (2 lesser curvature, 2 greater curvature), 2 from the cardia	S	++OO
	EMAG protocol should be sufficient for *H pylori* histologic diagnosis	S	++OO
Autoimmune metaplastic atrophic gastritis*	Individualize approach. Biopsies directed at ulcers, nodules, polyps, masses to rule out neoplasia	S	+OOO
Gastric polyps*	Solitary polyps Sample (biopsy or polypectomy). Further management determined by histology: Fundic gland polyp: >1 cm should undergo polypectomy† Hyperplastic polyp: >0.5 cm should undergo polypectomy‡ Adenomatous polyp: all should undergo polypectomy	S	++OO
	Multiple polyps Largest polyp removed with polypectomy Representative sampling of smaller polyps Further management dependent on histology	S	++OO
	For hyperplastic and adenomatous polyps Follow EMAG protocol Biopsies of surrounding nonpolypoid mucosa	S	++OO
Peptic ulcer	Multiple biopsies from the base and edges of a gastric ulcer when malignancy is suspected or	S	++OO

Disease	Tissue Sampling	Strength	Evidence
disease	suggested by endoscopic appearance. Cytology may be complementary		
	Perform biopsy protocol for *H pylori* as above	S	++OO
Small intestine			
Celiac disease	4-6 biopsies in total from duodenal bulb and distal duodenum	S	++OO
Colon			
Microscopic colitis	2 approaches: 1. FS: ≥2 biopsies from the transverse colon (if possible) ≥2 biopsies from the sigmoid colon ≥2 biopsies from the descending colon	S	++OO
	or		
	2. Colonoscopy ≥2 biopsies from the right colon ≥2 biopsies from the transverse colon ≥2 biopsies from the descending colon ≥2 biopsies from the sigmoid colon	S	++OO
	A nondiagnostic FS should be followed by colonoscopy with biopsy, pending clinical suspicion	S	++OO
IBD*	Initial diagnosis Ileocolonoscopy: ≥2 biopsies from at least 5 sites, including the ileum and rectum	S	++OO
	If EGD performed for suspected IBD: ≥2 biopsies from the esophagus ≥2 biopsies from the stomach ≥2 biopsies from the duodenum	S	++OO
	Surveillance for dysplasia: all endoscopically visible lesions should undergo biopsy and/or be removed	R	++++
	2 approaches: 1. Chromoendoscopy with pancolonic dye spraying and targeted biopsies. Also, biopsies from each colonic segment to assess inflammation.	R	+++O
	or		
	2. Pancolitis§: 4-quadrant biopsies every 10 cm from the cecum to the rectum, for a minimum total 33 biopsy samples	S	++OO
	Nonpancolitis§: 4-quadrant biopsies every 10 cm limited to greatest extent of endoscopic or histologic involvement documented by any colonoscopy	S	++OO
	Suspected pouchitis Multiple biopsies from the pouch and afferent limb	S	++OO
Miscellaneous			
Acute graft-versus-host disease*Ç	2 approaches: 1. FS ≥4 standard forceps biopsies from the rectosigmoid; ≥4 standard forceps biopsies the from left colon If FS nondiagnostic, proceed to EGD¶ with ≥4 standard forceps biopsies each, from the gastric antrum, gastric body, and duodenum Distal esophageal biopsies may be considered	S	++OO
	or		

Disease	2. Ileocolonoscopy Tissue Sampling	S Strength	++OO Evidence
	≥4 standard forceps biopsies from the terminal ileum ≥4 standard forceps biopsies from the right colon ≥4 standard forceps biopsies from the transverse colon ≥4 standard forceps biopsies from the left colon ≥4 standard forceps biopsies from the rectosigmoid		

Abbreviations: S, "The Practice Committee suggests"; R, "The Practice Committee recommends"; BE, Barrett's esophagus; EG, eosinophilic gastroenteritis; EMAG, environmental metaplastic atrophic gastritis; EoE, eosinophilic esophagitis; FS, flexible sigmoidoscopy; GERD, gastroesophageal reflux disease; HGD, high-grade dysplasia; IBD, inflammatory bowel disease; IHC, immunohistochemistry; LGD, low-grade dysplasia; PCR, polymerase chain reaction.

Recommendations in this table are as specific as published literature allows. Consensus recommendations often do not exist. Comparative effectiveness and cost-effectiveness studies were not available to guide tissue sampling suggestions. As a general principle of tissue acquisition, the Practice Committee suggests that specimen collection devices used to sample malignant tissue not be subsequently used on normal tissue to minimize the theoretical possibility of malignant contamination. For all conditions, in addition to the protocol listed, targeted biopsy samples should also be taken from any mucosal irregularities and sent in their own container for pathologic examination.

*Specimens taken from a given geographic location should be submitted to pathology in their own container.

†Recommendation is for a sporadic single fundic gland polyp that is not associated with familial adenomatous polyposis. Although sporadic fundic gland polyps have low to no malignant potential, expert opinion has been to remove fundic gland polyps larger than 1 cm. Withdrawal of a proton pump inhibitor (PPI) may be considered in patients with fundic gland polyps larger than 1cm.

‡If *H pylori* positive, treatment has been associated with regression of hyperplastic polyps.

§Consideration should be given to sampling every 5 cm in the distal colon.

ÇAlthough no hemorrhagic complications with biopsy were noted in the prospective literature, they have been reported in a retrospective study. Clinical judgment should be used to reduce number of biopsies if there is thought to be a significant bleeding risk.

¶Alternatively, pending clinical scenario, FS/EGD may be performed consecutively during a single endoscopic session.

Definitions:

GRADE (Grading of Recommendations Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

Quality of Evidence	Definition	Symbol
High quality	Further research is very unlikely to change confidence in the estimate of effect.	++++
Moderate quality	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	+++O
Low quality	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	++OO
Very low quality	Any estimate of effect is very uncertain.	+OOO

Adapted from Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.

Recommendation Strength

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Diseases of the digestive system requiring gastrointestinal endoscopy and mucosal tissue acquisition:

- Gastroesophageal reflux disease (GERD)
- Barrett's esophagus (BE)
- Eosinophilic esophagitis (EoE)
- Infectious esophagitis (viral, candidal)
- *Helicobacter pylori* gastritis
- Environmental metaplastic atrophic gastritis (EMAG)
- Autoimmune atrophic metaplastic gastritis (AMAG)
- Gastric epithelial polyps
- Peptic ulcer disease
- Celiac disease
- Microscopic colitis
- Inflammatory bowel disease
- Acute graft-versus-host disease

Guideline Category

Diagnosis

Evaluation

Management

Clinical Specialty

Gastroenterology

Internal Medicine

Oncology

Pathology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide guidelines for the use of gastrointestinal endoscopy in mucosal tissue sampling

Target Population

Patients undergoing gastrointestinal endoscopy and tissue acquisition for diagnosis or management of diseases of the digestive system

Interventions and Practices Considered

Gastrointestinal mucosal tissue sampling, including:

- Biopsy techniques
- Standard protocols
- Specimen handling

Major Outcomes Considered

Sensitivity, specificity, accuracy, and diagnostic yield of mucosal acquisition techniques

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

In preparing this guideline, a search of the medical literature within the date range of January 1993 to January 2013 was performed by using PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When few or no data exist from well-designed prospective trials, emphasis is given to results of large series and reports from recognized experts.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

GRADE (Grading of Recommendations Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

Quality of Evidence	Definition	Symbol
High quality	Further research is very unlikely to change confidence in the estimate of effect.	++++
Moderate quality	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	+++O

Quality of Evidence	Definition	Symbol
Low quality	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	+OOO
Very low quality	Any estimate of effect is very uncertain.	+OOO

Adapted from Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time that the guidelines are drafted.

Rating Scheme for the Strength of the Recommendations

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document is a product of the Standards of Practice Committee. This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Gastrointestinal endoscopy and tissue acquisition are fundamental to the diagnosis and management of diseases of the digestive system. The proper collection of tissue specimens is required for accurate pathologic diagnosis.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time that the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline.
- This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Aug

Guideline Developer(s)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

Source(s) of Funding

American Society for Gastrointestinal Endoscopy

Guideline Committee

Standards of Practice Committee

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Financial Disclosures/Conflicts of Interest

The following authors disclosed financial relationships relevant to this publication: Dr. Jain is a consultant to Boston Scientific and has received research support from Barrx. Dr. D. Fisher is a consultant to Epigenomics. Dr. Hwang is a consultant to U.S. Endoscopy and a speaker for Novartis. Dr. Pasha has received research support from CapsoVision. The other authors disclosed no financial relationships relevant to this publication.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy (ASGE) Web site .

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 11, 2013.

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